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21st century bioeconomy: global challenges of biological knowledge for health and agriculture

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Abstract

Investment in biotechnology has yielded relatively disappointing results and illustrates the gap between the promise and reality of new science. This begs the question: Does research on 'life' bring different complexities and uncertainties that act as a barrier to the application of new biology in global health and agriculture? There has been high quality research on the social and ethical impacts of new biology and on the economics of biotechnology, but few systematic and integrated attempts to undertake interdisciplinary research and address these constraints. This paper provides an original empirical analysis of contemporary and future understandings of the bioeconomy using a co-evolutionary and interactive approach to examine the extent to which it may be different from other technological transformations. We focus on the Innogen Centre's extensive research results on three important and contemporary themes – food and energy security, life science and healthcare translational medicine, and global health.

1 Background and context

Twenty-first century bioscience and bioeconomy promise solutions to the major global challenges of health and agriculture. Influential reports suggest that bioscience and its application can meet these global challenges so that biological knowledge becomes crucial for a wide range of social and economic transformations (OECD 2009, National Research Council 2009). These reports argue that biological advances (in science, technology and innovation) will hugely influence social, economic and cultural change. However, the benefits of new biology have been promised for a while. Analyses tend to overestimate the speed and extent of changes associated with new biology (Hopkins et al 2007, Orsenigo and Tait 2008), which begs the question of whether the new biology and the broader bioeconomy is just a long time coming or if there are deeper and more fundamental constraints.

In this paper we explore the emergence of new biology through three cases and reveal fundamental constraints that are holding back the evolution of the biosciences and their applications. We use the term new biology in an inclusive way to mean increasing integration of biology, not only molecular biology, with informatics and the social sciences. We use the term life science to describe the integration of biological science, technology and innovation within the broader bioeconomy. The bioeconomy refers to the set of economic activities relating to the invention, development, production and use of biological products and processes (OECD, 2009)

We investigate the extent to which new biology is ‘different’ to other areas where science and technology influence societal changes. Does biological research, with applications in ‘life’ bring different complexities and uncertainties that are slowing applications in health and agriculture? We will show the importance of taking a co-evolutionary and interactive interdisciplinary approach to analysis of the life sciences (Van der Ven and Garud 1994). Rather than a frame that focuses on how major biological advances may influence society, economy and culture, we assume that science and social science can co-evolve. We use a framework identified in the 1990s and used in the decade from 2002 in the Innogen Centre (Wield, 2008). The framework was developed to engage with the increasingly systemic integration of, and interactions between: innovation; governance and regulation; and publics (Tait, 1990; Wield, 2008).

This framework allows us to analyse the relationships in life sciences. We hypothesise that innovation in new biology requires new types of social and institutional arrangements between – and within – three main sets of actors that drive innovation:

1. The extremely complex group of actors involved in the production of science, technology and innovation in research settings, companies, and new collaborative networks and partnerships;
2. Policy makers and regulators – from narrowly organised regulatory bodies for sub-parts of the innovation system, to those responsible for bridging boundaries and proposing regulatory innovation;
3. Citizens and ‘stakeholder’ groups (such as patient interest groups and advocacy organisations) who provide an important ‘check’ on the other two sets of stakeholders, for example concerning gm crops and drugs advocacy for HIV/AIDS sufferers.

This co-evolutionary approach, which recognises the interconnection of different actors and events in shaping the current and future possibilities of the biosciences, underpins the framing of this paper and the research it draws upon. Life science research, and associated research on the social and economic nature of the life sciences, necessarily requires interdisciplinary methods and capabilities. The approach we have developed, including in this paper, provides three key insights. First that innovation in the life sciences requires knowledge from multiple sources, in a more ‘open’ way, including from users of knowledge, such as patients. Second, innovation involves different sources of knowledge interacting with each other in an interdisciplinary way such that ideas are shared and combined. Third, these interactions are normally specific to a particular context, and each context has its own routines and traditions, as we see from the three cases below.

There is evidence that new biology does differ from other sciences. Dupre (1995) has made the important observation that science looks disunified as explored through biology. Biology, unlike sciences such as physics and chemistry that have historically been favoured in philosophies of science, does not look like it has methodological unity or underlying theory to link the disparate fields under its domain. There is also evidence that investment in application of new biology (biotechnology), has, so far, had disappointing results (Pisano, 2006). The reasons include that research on biology and the development of biological applications have layers of regulation that are stringent and lengthy. Major drug-use disasters have led to regulatory regimes that dominate the structure of bio-economic organisations and institutions, in universities, research institutes, big pharmaceutical and small biotech companies, and health and food institutions. Furthermore, in health in particular, market systems are highly structured with weaker direct consumer marketing and large national and managed health care systems and policy.

We analyse the changes brought by new biology in three thematic cases: food and energy security; translational medicine; and global health. The rationale for these specific thematic areas is that they are exemplars of the different ways in which the new biology co-evolves with social, economic, industrial and cultural change. They also highlight the crucial importance of ‘context’ for the configuration of broader systemic processes. In other words, the state of biological knowledge production and application is such that it is transformative of health and agriculture but is contingent upon, among other things, the co-evolution of, and interaction between, different industries and the resultant products of their R&D; the local and global political economy of complex multi-agent knowledge production; and different public attitudes to risk and benefit. The next sections (2-4) focus on the three cases introduced above, followed by a conclusions section 5.

2 Food and energy security

The food and energy case is an exemplar of our theoretical and empirical approach. Its focus is the co-evolution of industrial, social and regulatory processes concerning food security and sustainable development in developed and developing economies. Food production includes the development of new molecular biology, but depends crucially on interdisciplinary integration between natural and social scientific knowledge; and between multiple actors, including scientists, industry, regulators and policy makers, and various public interest coalitions.

Agricultural production will face enhanced existing and new pressures in the future. Agriculture is presently responsible for feeding seven billion global citizens and estimated to rise to 9.5 bn by 2050. In 2009, for the first time, over one billion people were classified as food insecure by the UN Food and Agriculture Organisation (FAO, 2009), partially due to increased production of crops for biofuels, knock-on changes in land use and commodity speculation. Agricultural science involves the slow introduction of new agrichemical products, because of the need for tight regulation of food products. The integrated introduction of new seeds and chemicals also requires lengthy trials. The time needed for agrarian change is dramatically determined by extension and promotion policies. Governments have been key to accelerating the process of agrarian change, not least in the recent rapid biofuels growth.

Plants are increasingly used as raw materials for new forms of energy production. They have been integrated into new energy-focused production systems, such as sugarcane in the production of bioethanol or *jatropha curca* in the production of biodiesel. Plants as a source of bioenergy present new challenges for the biosciences: genetic modification may produce plants that yield more energy or lead to the development of 'second generation' biofuel crops that will not impact upon food security, or the promise of cheaper land and labour in parts of the global south may undercut the demand for much new R&D (Nuffield, 2011).

Our research evidences that new biology is beginning to impact on food production. Companies, organisations and institutions are co-evolving as new biology is incorporated into products and processes (Smith, 2010). This is not new. In a previous period of rapid change, the green revolution brought new hybrid crop varieties. But results were hugely differentiated by geography, crop type, and by the ability of producers to invest in surrounding technical and economic infrastructure to promote higher crop yields and systemic change. Present transformation includes step changes in other conditions, such as: increasing corporate integration and monopolisation of the food value-chain; the emergence of new configurations of food-fuel hybrid value chains and new technologies, including gm crops.

New biology has begun to transform the food and agriculture sectors. Our research shows that, at the level of industrial processes, companies previously dominated by chemistry are now increasingly drawing on biology and have large interdisciplinary science and business teams (Chataway et al, 2004, 2006; Wield et al 2010). Agri-chemical and seeds companies, which were previously separate entities with a high degree of independence (the former historically more profitable than the latter), are now tightly integrated. New science and technology has co-evolved with new actors to bring novel organisational and institutional forms, such as large agricultural public-private partnerships integrating researchers, industries, donor funders and farmers, to generate new plant breeding techniques useful in developing as well as advanced countries (Wield et al, 2010).

More generally, R&D and animal and crop production systems are beginning to respond (prompted by incentives, markets and governance systems) to the realisation that climate change, global interconnectedness, global energy requirements and new biological technologies may bring profound environmental changes in a period of food and energy insecurity (Smith, 2010). These challenges are leading to significant public and private sector

investments in research, although thoughtful governance of these rapidly evolving global systems lags behind investment and incentives to adopt biofuel.

Our results also evidence the important role of food and energy security issues in the framing of new biology and how that influences the research agenda (Ayele and Wield, 2005; Wield et al, 2010). We have detailed changing public policy and strategic management issues in research development and innovation in the most relevant industries (agro-chemicals, seeds, farming and retailing) (Chataway et al, 2004, 2006). We have analysed the rapidly changing risk regulatory agendas and their role in shaping global innovation networks (Tait 2007; 2008). We have also revealed the increased collaborative, interdisciplinarity changes in knowledge interaction in African public-private partnerships (Ayele et al, 2006), and in relationships between the Food and Agricultural Organization of the United Nations and civil society organisations in Africa, South Asia and Latin America (Smith and Chataway, 2009).

At the level of national policy we have investigated bioenergy policymaking processes in East Africa and South Asia. In Kenya, we co-convened (with the African Centre of Technology Studies) a Policy Working Group that brought together all actors to help develop the national strategy paper for both biodiesel and bioethanol (www.pisces.or.ke). Given the complexity of issues and interactions, driven by both new science and new investment, and the range of interested actors - spanning the public sector, the private sector, non-governmental organisations, and actors from Kenya and well beyond - generating appropriate, strategic responses to the promises and risks of biofuels is important (Smith, 2010). The approach is now being used in East Africa and in Sri Lanka, drawing heavily on our interdisciplinary, participatory approach to the production of new knowledge.

The key issues that emerge from our fieldwork in Europe and Africa are the intensification of food production, fibre and energy crop production, the management of natural resource and preserve biodiversity, rural economy and increased multi-functionality of land use. But, contrary to the dominant food and energy security discourses our research illustrates that these issues cannot easily be treated as single elements separated from others, there is no single food system. Instead, there are multitudes of fluid, diverse, sensitive and ephemeral systems that serve different markets, are based on different agro-ecological conditions and are beholden on complex sets of policies, markets and other external stimuli. Empirically, rather than focusing on food and energy security, we suggest that an improved approach is to focus on understanding the specifics of food *insecurity*. Each transformation brings new organisations and institutions coupled with new knowledge forms, dramatically increasing the complexity and inter-disciplinarity of production and consumption systems. Understanding these is a prerequisite for building understanding of how to improve security of livelihoods.

3 Translational medicine

Translational medicine (TM) is our second illustrative case study. The concept of TM has emerged in clinical, scientific and health policy communities to describe new sets of technological and organisational processes needed to better exploit life science innovations for healthcare delivery. One key foci has been the need for new collaborative research environments and regulatory/policy changes to facilitate innovation of new therapies, which despite the promise of life science has not kept pace with increased R&D investment.. TM

aims to bridge gaps in the health innovation pathway. The language of ‘bed to bedside and back again’ research is a key feature of TM, although its precise definitional status and methods of implementation have been quite broad (Butler, 2008; Fitzgerald, 2008). TM necessarily requires a co-evolutionary and interactive approach since, as a set of interdisciplinary practices it must bring together complex networks of researchers, companies, health services and patients if it is to generate innovation. Bringing such groups together is happening, but it remains a challenge given the different styles of research (for example, wet lab science – *in vitro*, *in vivo*, dry informatics – *in silico*, and epidemiology, and social health care research) and different styles of relationships with ‘users’.

A key driver of TM is the ‘productivity crisis’ and high attrition of new therapeutic compounds and the significant and diverse global challenges facing 21st century healthcare (Tait & Mittra, 2004; Mittra, 2007, 2008). TM emerged in the mid 1990s as a response to concern that despite the wealth of knowledge and expertise on the cellular and physiological mechanisms of many debilitating and fatal diseases, few novel treatments were making it through to the clinic. A number of causes were identified. On the clinical side, there were few opportunities for practitioners to bring clinical findings and key insights from the bedside to the attention of predominantly lab-based research scientists. On the research side, the underlying connections between study results from *in vitro*, *in vivo* and *in silico* studies were not being made; and animal models and simulation programs were of insufficient predictive value to understand the human condition (Mittra & Milne, 2012).

Our research has aimed to understand better the new interdisciplinary relationships and the extent to which co-evolution of knowledge is occurring. It shows that scientists, industry and regulators are the main drivers of change and change in practices is most striking in the new public-private initiatives. Examples include the Translational Medicine Research Collaboration (TMRC) in Scotland and the Center for Translational Molecular Medicine in the Netherlands. Scientists and clinicians are embracing TM predominantly to better understand and exploit the range of new technologies emerging from the life sciences, and enhance the interface between basic science and clinical medicine, whereas industry sees the value of TM in its ability to reduce the attrition rate of new drugs and reduce costs of R&D. Regulators see the value of TM in its ability to contribute to safer and more effective drugs. TM advocates suggest that the key is in the mechanisms to coordinate the disparate activities and knowledge domains constitutive of life science innovation, of which TMRC was an exemplar.

The TMRC was established in 2006 to develop a world leading network of clinical and scientific excellence in Scotland. As a large-scale collaboration between industry, government and academia, the initiative received initial funding of £50 million for 5-years of research from April 2006-2011. It involved four research strong medical schools; national health board; Scotland’s economic development agency Scottish Enterprise, and the pharmaceutical firm Wyeth. The idea was to set up a translational initiative beyond the preclinical phase. TMRC was an example of a promising collaborative project with a high degree of institutional buy-in to tackle translational issues in health innovation. Company take-overs led to the loss of the private company But the case study offers lessons and about the institutional infrastructures and organizational relationships needed for TM to fulfill its promise of improving healthcare innovation and meet the diverse needs of key stakeholders (Mittra, 2012).

We have investigated many other relevant reorganisations of R&D within the pharmaceutical industry, and the emergence of novel public-private partnerships for health innovation (Mittra and Williams, 2007; Orsenigo and Tait, 2008). For industry, TM has taken on several meanings and consequently TM units within major pharmaceutical companies have taken different forms. In some, dedicated TM groups have tried to create a more direct connection between basic research and patient care, i.e. addressing questions related to how the therapies actually work in the clinical setting. For others, the key objective has been to bridge the gap from late discovery to early clinical development so that decisions on product candidates can be managed on a more evidence-based footing. For others, TM units can serve as conduits for accessing external, often experimental, R&D resources either through a consortium of research partners or academic collaborations into new public-private partnerships; the idea being that sharing resources, skills and expertise, as well as risks associated with drug development, can enhance R&D (Mittra & Milne, 2012). Industry believes TM, and the interdisciplinary resources and expertise it encourages, will make positive contributions to the drug discovery and development processes to R&D costs and timescales (Mittra, 2008).

Major concerns of regulators, (and politicians and the public) are the cost, safety and efficacy of new therapeutic products. Pharmaceutical research and product development is subject to an extremely high ‘regulatory hurdle’, which is continually changing. New life science technologies are helping to identify novel compounds and improve their safety and efficacy profiles. Technology is also helping to improve the delivery of compounds to relevant disease targets. The integration of basic and clinical knowledge and expertise early in the development pathway, through new translational processes, can also be seen as an attempt to meet increased regulatory requirements and societal expectations.

As with food and energy then, ‘translation’ presents a number of complex issues, questions and opportunities for exploring the future of biomedical innovation in a global context, which we have been developing through our research. In this thematic area we have addressed issues around the strategic management and sustainability of commercial pharmaceutical innovation in the context of new biology and emerging regulatory systems built around it (Mittra, 2008); the general framing of regulation, risk and public health policy and their role in shaping global innovation networks; and the emergence and exploitation of interdisciplinarity in both public and private knowledge production processes.

4 Global Health

Just as there has been recognition of the need to think about ‘translation’ generally, so there is growing recognition that access to new innovations depends not only on excellent basic bio-science but also on finding new ways to bring together scientists, health professionals and social scientists globally to develop and experiment with new mechanisms that may better integrate health innovation and health systems. Our previous research (Chataway et al, 2009, 2011; Hanlin and Sutz, 2010) has shown the profound gulf between researchers working on life science innovation and researchers in other levels of health systems.

This is despite the fact that resources devoted to global health have increased tremendously over the past decade (development assistance for health was estimated to have reached \$26.87 billion by 2010 (IHME, 2010)) as new funders, such as large foundations like the Bill and Melinda Gates Foundation, have joined other donors to build huge new health research

and innovation institutions and public-private partnerships. These new forms of collaboration have brought together a variety of stakeholders not only in the form of private pharmaceutical companies with donors, but also non-governmental organisations, patient and consumer groups providing the opportunity for a range of voices to be heard throughout the research-development-access continuum of health innovation.

They have driven traditional actors, such as aid donors and multilateral agencies like the WHO and UNICEF, with other stakeholders, to develop new ways to bridge the translational medicine gap that is particularly profound in the area of global health. In particular, where products are produced for diseases effecting the poorest in society who are unable to pay for medicines and often in developing countries where health systems struggle, there is weak market incentive for private pharmaceutical companies to invest in drug, vaccine and diagnostic development. In particular, the R&D world associated with these ‘neglected diseases’ has become proliferated with what have become known as ‘Product Development Partnerships’ (PDPs) which at their height in the late 2000s took over 20% of the total R&D funding for neglected diseases. There is also increasing recognition that health impacts, and is impacted by, other issues. This includes a strong relationship between agriculture and health which is equally mirrored by crossovers in their innovation activities (Hawkes and Ruel, 2009). Yet, the ways in which health related innovations (particularly diagnostic methods, drugs and vaccines) evolve and touch the lives of people will depend on numerous and complex ways in which the gaps can be bridged between innovation and health systems but also agriculture, finance and education systems.

Our research with colleagues around the world has aimed to bring greater critical analysis and understanding of how health systems can be strengthened through the activities of life science PDPs. This builds on the translation theme by asking how specific partnerships can reduce global disease burden, especially that affecting the poorest populations in the world. More directly, we have asked how innovation can transform access to medicines.

Building on frameworks such as those used in our food and energy research, and on our actor interaction framework (Wield 2008), to analyse relationships between innovators, regulators and publics; we have built an understanding of how PDPs have been so successful at promoting the development of new biology for neglected diseases in global health. The key aspects of this concept are that it recognises, first, the variety of actors involved in making innovation activities successful in the life sciences and, second, the value of facilitating organisational arrangements (such as coordinating not-for-profits and ensuring frequent communication opportunities between scientists working at all stages of the product development pipeline) but also institutional mechanisms (especially supportive policy and regulatory environments).

Our work has provided empirical evidence of the need for ‘joined up’ interdisciplinary thinking between multiple actors from both within and outside science. In particular, our research of PDPs (Chataway and Smith, 2006; Hanlin, 2009; Chataway et al, 2007; Chataway et al, 2011) involved in AIDS and malaria vaccine research in Africa and India highlights the existence of tensions between different groups involved. These partnerships were created because of the recognition that more joined up thinking was needed to get a vaccine from ‘bench to bedside’. Coherence was to emerge by bringing together global forms of

knowledge of new biology, systems of governance and expertise of markets. Actors were assembled from these different worlds into an interdisciplinary assemblage – the product development partnership - to develop therapies against neglected diseases. As with TM partnerships and food and energy alliances, global health PDPs were developed with the aim of bringing together not only all the best scientists involved in neglected disease research but also those working in public health, community development, and end users.

Precisely as imagined in our problematisation of the life sciences, progress could only take place by building networks both of different types of natural scientist and also social scientists, producers and users to co-evolve new technologies of product delivery for neglected diseases. We researched various sites for integration in PDPs. We have studied clinical trial sites in developed and developing countries where clinical research was taking place. We also studied the headquarters of one of the partnerships. We have shown how tensions are played out in both types of site (Cacciatori et al, 2010) and have described how PDPs have become adept at managing these tensions at a range of scales in order to successfully apply bioscience knowledge to real-world problems (Chataway et al, 2007).

This empirical work has brought conceptual thinking on the ways in which collaborations between stakeholders involved in global health combine and interact. We have contributed to two specific areas. First, our empirical work on PDPs has led to a rethinking of the value of collaborative efforts in global health. Specifically, the degree to which having a coordinating mechanism is useful to develop the broking and integration of knowledge required in interdisciplinary research and action settings in order to involve all stakeholders, not just those in the scientific research arena (Chataway et al, 2007; Chataway et al, 2011). Second, we have contributed to thinking about the policy landscape that best promotes interdisciplinary activity of this nature. This research on health innovation systems thinking (Chataway et al, 2009) highlights the importance of thinking outside of traditional disciplinary boundaries at the policy level and emphasises the importance of including a wider range of policy areas in discussions of innovation in order to effectively promote life science innovation that reaches the bedsides of the poorest in society.

5 Discussion and Conclusions

We have investigated how new biology co-evolves with and changes life science economy, organisations and institutions (the bioeconomy), in what ways new biology is specific and different, and how different contexts matter? We have used a theoretical framing that interweaves theories of: the life sciences; innovation, particularly innovation in networks and partnerships; and, the complex regulatory regimes within which bioscience and technology take place. Our argument bears out that the big issues come from interactions between the three main sets of actors: innovators (scientists, technologists, industry); policy makers and regulators (including government and the emerging new institutions of governance); and public and stakeholder groups.

Our research on life science and innovation networks in food and energy security, translational medicine, and global health has been able to throw light on what might be constraining life science and also possible improvements. We will summarise how our empirical research suggests further ways forward in:

- 1 Social theorisation of new biology and the life sciences, particularly of the importance of interdisciplinarity, complexity and context differences;
- 2 Social theories of innovation systems, particularly regarding innovation dynamics (in single organisations, networks and partnerships) and innovation strategies; and
- 3 Social theory of the relationships between, on the one hand, science and innovation, and on the other, regulatory regimes and governance systems.

Social science of new biology and the life sciences

New biology introduces a new degree of objectification to living matter (eg embryos, animal integrity). Living things reproduce (as with gene flow from genetically modified organisms - gmos) which brings novel implications for risk regulation and intellectual property. The long timeframes involved in life science innovation introduce promissory issues and the management of expectations (Borup et al, 2006) but we don't know how to evaluate promises which may completely fail but can also overwhelm all other evolutionary paths. Developing viable business models is difficult in such circumstances.

Interdisciplinarity in biology is rather well developed, and now includes the bringing together of informatics and biology (bioinformatics, systems biology, synthetic biology). By comparison, interdisciplinary social study of new biology is less advanced (Barry et al 2008, Greaves and Grant 2010, Lyall et al, 2011). Barry et al suggest that interdisciplinary collaboration of science with social science is driven by three underlying logics; the logic of accountability, where social sciences are expected to enhance accountability of science; logic of innovation, making it more linked to users; and logic of ontology, challenging narrow understandings of technical objects. The interdisciplinary, highly collaborative practices in our study suggest that new configurations are emerging that will prefigure new epistemic cultures – communities of practice with language, beliefs and routines. Interdisciplinary research that integrates social and natural sciences will be needed to better understand future changes.

Social theories of innovation systems

Innovation is traditionally studied as a firm-based activity, in sectors where firms strive to integrate R&D into new products and processes (Freeman and Soete, 1997). Traditionally, nations strategise about improving their competitiveness (Porter, 1998). But increasingly, innovation has become understood as something that happens within a range of social and economic activities, in services, in clusters and networks as well as sectors and regions. The life sciences are an exemplar to allow investigation of such approaches to innovation. They encompass big pharmaceutical companies – a traditionally high R&D sector which is now maturing rapidly, new biotech firms, innovative financing systems, but also a range of innovative institutional arrangements such as public-private partnerships for orphan and neglected drugs, complex regulation and patient-included research networks (Orsenigo and Tait 2008, Mittra and Williams 2007).

Our research on innovation dynamics allows broadening of conceptualisations of innovation strategies, including types of policy frameworks, regulatory regimes and global configurations such as public-private partnerships for product development of new therapies such as vaccines (Chataway and Smith, 2006). This provides insights, first that innovation requires knowledge from multiple sources, in a more 'open' way, including from users of

knowledge. Second, innovation involves different sources of knowledge interacting and co-evolving. Third, these interactions are normally specific to a particular context, and each context has its own routines and traditions.

The relationship between innovation and regulation

Regulation has major influences on innovation processes. Regulation appropriate to one policy area and context can have negative impacts in other contexts. Innogen research, analysing the relationship between innovators, policymakers and regulators; and citizens, has shown that regulatory systems can, by a series of incremental changes over time, become increasingly out of step with the regulated area, and also become increasingly complex so that a change or addition can have unexpected implications (Tait et al, 2007, Chataway et al 2006). As a regulatory regime becomes more complex and hierarchical, its practices likely become more fragmented. Regulators are in the midst of competing demands from interests, values and power of organisations and regulation has become a multi-institution activity that can therefore be analysed in a similar way to more open innovation processes and more collaborative knowledge systems. The regulatory practices of all groups described above can influence the relationship between innovation and regulation.

In conclusion, the emergence and development of bioscience and rapid growth of the bioeconomy, as well as the constraints, depend on interactions between three main sets of actors, and on the consequent co-evolution of life science, technologies markets, governance systems and users. This necessarily depends on the growth not only of new, more open, forms of knowledge but on new forms of interdisciplinarity interaction that go beyond a straightforward integration of scientific knowledge but on the co-evolution of knowledge with the social sciences. The specifics of new biology, detailed in three cases, imply that the 21st century bioeconomy depends on the development of new interdisciplinary capabilities.

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REFERENCES

- Ayele, S and Wield, D. (2005) 'Capacity Building and Public-private Partnerships in African Crop Development', *Journal of International Development*, 17/5, 631-636.
- Ayele, S., Chataway, J and Wield, D. (2006) 'Partnerships in African Crop Development and the Millennium Development Goals', *Nature Biotechnology*, 26, 619-621.
- Barry, A., Born, G., Weszkalnys, G. (2008) 'Logics of interdisciplinarity', *Economy and Society* 37/1, 20-49.
- Borup, M., Brown, N., Konrad, K., Van Lente, H. (2006) 'The sociology of expectations in science and technology', *Technology Analysis and Strategic Management*, 18/3-4, 285-298.

- Butler, D. (2008) 'Crossing the valley of death', *Nature*, 453, pp. 840-842.
- Cacciatori, E., Hanlin, R., Breschi, S., Brusoni, S. and Orsenigo, L. (2010) 'The uneven development and distribution of vaccines across cultures: the case of AIDS' Final report of Work Package 7 of *Culture and Innovation Dynamics*
http://portale.unibocconi.it/wps/wcm/connect/Centro_KITES/Home/Research+Networks/CI/D/Deliverables/ accessed 7 Oct 2012.
- Chataway, J., Tait, J and Wield, D (2004) 'Understanding company R&D strategies in agro-biotechnology: trajectories and blind-spots', *Research Policy*, 33/6-7, 1041-1057.
- Chataway, J., Tait, J., Wield, D. (2006) 'The governance of agro- and pharmaceutical biotechnology innovation: public policy and industrial strategy', *Technology Analysis and Strategic Management*, 18/2, 1-17.
- Chataway, J. and Smith, J. (2006) 'The International Aids Vaccine Initiative (IAVI): is it getting new science and technology to the world's neglected majority?', *World Development*, 34/1, 16-30.
- Chataway, J.C., Brusoni, S., Cacciatori, E., Orsenigo, L. and Hanlin, R. (2007) 'The International AIDS Vaccine Initiative (IAVI) in a changing landscape of vaccine development: a Public Private Partnership as knowledge broker and integrator' *European Journal of Development Research*, 19/1, pp. 100-17.
- Chataway, J.C., Chaturvedi, K., Hanlin, R., Mugwagwa, J.T., Wield, D. (2009) 'Building the case for national systems of health innovation', In Kalua, F. et al (eds.) *Science, Technology and Innovation for Public Health in Africa*, 7-52, NEPAD, NEPAD Office of Science and Technology, Pretoria.
- Chataway, J.C., Hanlin, R., Mugwagwa, J. and Muraguri, L. (2011) 'Global health social technologies: Reflections on evolving theories and landscapes' *Research Policy* Vol. 39/10, 1277-1288.
- Dupre, J. (1995) *The Disorder of things: metaphysical foundations of the disunity of science*, Cambridge, Mass.: Harvard University Press.
- FAO (2009) *The state of food insecurity in the world, 2009*, Rome: FAO.
- FDA (2006) *Critical path opportunities report*, US Department of Health and Human Services, March.
- Fitzgerald, G. (2008) 'Drugs, Industry and Academia', *Science*, 320, 1563.
- Freeman, C. and Soete, L. (1997) *The Economics of Industrial Innovation*, London: Pinter.
- Greaves, J. and Grant, W. (2010) 'Crossing the interdisciplinary divide: political science and biological science', *Political Studies* 58, 320-339.
- Hanlin, R. (2009) 'International Product Development Partnerships: Innovation for better health?' *RECIIS*, 3/4, 198-208.
- Hanlin, R. and Sutz, J. (2010) 'Where are the flags of our fathers? Rethinking linkages between social policies and innovation policies', *African Journal of Science, Technology and Innovation for Development*, Vol. 2/3, 153-169.
- Hopkins, M.M., Martin PA., Nightingale, P., Kraft A., Mahdi, S. (2007) 'The myth of the biotech revolution: an assessment of technological, clinical and organisational change', *Research Policy* 36/4, 566-589.
- Hawkes, C., Ruel, M.T. (2009) 'The links between agriculture and health : an intersectoral opportunity to improve the health and livelihoods of the poor', In Kalua, F. et al (eds.) *Science, technology and innovation for public health in Africa*, 111-122, Pretoria, NEPAD Office of Science and Technology.
- IHME (Institute for Health Metrics and Evaluation) (2010) *Financing Global Health 2010: Development assistance and country spending in economic uncertainty*. Seattle, WA: IHME.

- Lyall, C., Bruce, A., Tait, J and Meagher, L (2011) *Interdisciplinary Research Journeys: Practical Strategies for Capturing Creativity*, London: Bloomsbury Academic.
- Mittra, J. and Williams, R. (2007) *Special Issue: Evolution of the Life Science Industries, Technology Analysis and Strategic Management*, 19/3.
- Mittra, J. (2007) 'Life Science Innovation and the Restructuring of the Pharmaceutical Industry: Merger, Acquisition and Strategic Alliance Behaviour of Large Firms', *Technology Analysis and Strategic Management*, 19/3, 279-301.
- Mittra, J. (2008) 'Impact of the Life Sciences on Organisation and Management of R&D in Large Pharmaceutical Firms', *Int. J. Biotechnology*, 10/5, 416-440.
- Mittra, J. (2012) 'Exploiting Translational Medicine Through Public-Private Partnerships: a Case Study of Scotland's Translational Medicine Research Collaboration (TMRC),' in J. Mittra & C. Milne (eds) *Translational Medicine: The Future of Therapy?* Singapore: Pan Stanford Publishing (forthcoming).
- Mittra, J. & C Milne (2012) 'Introduction to Translational Medicine', in J. Mittra & C. Milne (eds) *Translational Medicine: The Future of Therapy?* Singapore: Pan Stanford Publishing (forthcoming)
- National Research Council of the National Academies (2009) *A new biology for the twenty-first century*, Washington DC: National Academies Press.
- Nuffield Council on Bioethics (2011) *Biofuels: ethical issues*, London: Nuffield Press.
- OECD (2009) *Bioeconomy to 2030*, Paris: OECD.
- Orsenigo, L. and Tait, J. (2008) *Special Issue, Evolution of the Life Science Industries, Int. J. Biotechnology*, 10/ 5.
- Pisano, G. (2006) *Science business: the promise the reality and the future of biotech*, Boston: Harvard Business School Press.
- Porter, M. (1998) *Competitive advantage of nations*, New York: Free Press.
- Smith, J. and Chataway, J. (2009) 'Learning from the Periphery: the CGIAR and civil society partnerships', *Working Paper International Learning and Change Initiative*, CGIAR.
- Smith, J. (2010) *Biofuels and the Globalization of Risk: The biggest challenge in North-South relationships since colonialism*, London: Zed Books
- Tait, J. (1990) 'Biotechnology: Interactions between Technology, Environment and Society', *FAST Programme Synthesis Report No 1 Project*, July, EU Fast.
- Tait, J. (2007) 'Systemic interactions in Life Science Innovation', *Technology Analysis and Strategic Management*, 19/3, 257-277.
- Tait, J. (2008) 'Risk Governance of Genetically Modified Crops: European and American Perspectives'. In eds. O. Renn and K. Walker, *Global Risk Governance: Concept and Practice Using the IRGC Framework*. Dordrecht, NL: Springer Science and Business Media; pp 133-153.
- Tait, J. & Mittra, J. (2004) 'Industry Challenges', *Chemistry and Industry*, 6 December, No. 23, 24.
- Tait, J., Chataway, J., Wield, D. (2007) 'Appropriate governance of the life sciences 2', *Innogen Policy Brief*.
- Van der Ven, A. H. and Garud, R. (1994) 'The co-evolution of technical and institutional events in the development of an innovation', in Baum, J.A. and Singh, J.V. (eds.) *Evolutionary Dynamics of Organizations*, 425-443, Oxford University Press, New York, Oxford.
- Wield, D. (2008) 'The ESRC Centre for Social and Economic Research on Innovation in Genomics', *SCRIPTed*, 5/3, 3-7.

Wield, D., Chataway, J. and Bolo, M. (2010) Issues in the political economy of agricultural biotechnology, *J. Agrarian Change*, 10/3, 342-366.